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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,211	12/05/2001	Milton D. Goldenberg	IMMU:003US1	5605

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ROSSI, KIMMS & McDOWELL LLP.
P.O. BOX 826
ASHBURN, VA 20146-0826

EXAMINER	
CROWDER, CHUN	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/002,211	GOLDENBERG, MILTON D.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/09/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments, filed 12/18/2006, have been entered.

Claims 1-77 have been previously canceled.

Claims 85 and 86 have been amended.

Claims 93 have been added.

Claims 78-93 are pending and currently under consideration as they read on the originally elected species of ITP and LL2 antibody.

2. This Office Action will be in response to applicant's arguments, filed 12/18/2006.

The rejections of record can be found in the previous Office Action, mailed 08/17/2006.

3. The IDS, filed 02/09/2004, has been considered except the followings:

References B1-B7 have been crossed-out because they have been considered in the Office Action mailed 08/17/2006.

References B10, B17, B20-B22 have been crossed-out because they appear to be duplicates of those listed on IDS filed 12/04/2001 and have been considered in the previous Office Action mailed 08/17/2006.

References B16, B18, B19, B23-B27 have been crossed-out because applicant has not provided copies of those references.

Applicant further asserts that EP 03 07 6875 and EP 03 07 6876 are counterparts of the present application and the IDS, filed 06/09/2004 contains documents that were cited in the European search reports of these two applications. However, these two references have not been listed on the IDS, therefore, they are not considered.

Applicant is reminded that all foreign patent documents must be cited by document number (including kind code), country and publication or issue date on IDS; and copies of each cited foreign patent document and each cited non-patent literature publication must be provided. See MPEP 609.01.

4. The references Stein et al (abstract only), Coleman et al. and Goldenberg et al, submitted 12/18/2006 have been listed on PTO-1449. Applicant also submitted reference Dorner et al. (Arthritis Research& Therapy 2006, 8;3:1-11), however, it is not clear the relevancy of this reference because it has not been discussed in the Remarks, filed 12/18/2006, nor is it cited on IDS.

4. Applicant's amendments to the specification including a new title, filed 12/18/2006, have been entered.

5. The priority applications USSN 09/110,181 (now US Patent 6,331,175) and USSN 07/866,789 (now US Patent 5,776,093) upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 78-92 of this application. Specifically, insufficient support was identified for the limitation of "marker associated with a B cell" for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that page 15, lines 8-9 references that "the antibody is an antibody or antibody fragment which specifically binds a ***marker*** produced by or associated with said cell or tissue."; page 5, lines 19 and 20 describes "an antibody or antibody fragment specific to a marker associated with or produced by bone marrow cells," and page 12, lines 12-16 describes "antibodies and fragments against .... B-cells ...", and page 12, lines 30-33 discloses that antibodies that target the spleen well include the LL2, which is directed against normal and malignant B-cells. Therefore, applicant asserts that the parent application have support for the term "market associated with a B cell".

This is not found persuasive for following reasons:

In contrast to applicant's reliance on generic disclosure of antibodies and a single species LL2 antibody to support the claimed antibody or antibody fragment specific to "a marker associated with a B cell", the examiner acknowledges that there is insufficient support in the instant specification as well as the parent applicants for the term "a marker associated with a B cell". See discussion below in Section 10.

Consequently, the instant claims have been accorded the priority of the filing date of the instant application, i.e. 12/05/2001.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 87-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Claims 87-92 are indefinite in the recitation of "LL2 antibody"

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that "LL2 antibody" has been used in claims of several issued US Patents without any reference to SEQ ID NOs or Accession number; as such, applicant asserts that the term "LL2 antibody" is not indefinite.

This is not found persuasive for following reasons:

It is well settled that whether similar claims have been allowed to others is immaterial. See In re Giolito, 530 F.2d 397, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini 21 USPQ2d 1892, 1897 (BPAI 1991). Each application is examined on its own merits. Further, The use of "LL2 antibody" as the sole means of identifying the claimed antibody renders the claim indefinite because "LL2 antibody" is merely laboratory designation which does not clearly define the claimed product, since different a laboratories may use the same designation to define completely distinct biological materials.

Applicant is once again suggested to amend the claims to recite the appropriate Deposit Accession Number or SEQ ID NOs to obviate this rejection.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 87-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

It is apparent that the LL2 antibody, recited in claims 87-92, is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, a deposit of the hybridoma, which produces this antibody, may satisfy first paragraph. See 37 CFR 1.801-1.809.

Given the absence of rebuttal to the outstanding rejections of record in applicant's amendment, filed 12/18/2006, the rejection is maintained for reasons of record.

See previous Office Action, mailed 08/17/2006, for detailed analysis.

10. Claims 78-92 and newly added claim 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record.

This is a *Written Description*, New Matter rejection.

The terms "a marker associated with a B cell" recited in claims 78-93 are not supported by the original disclosure or claim as filed.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that the specification includes more than a disclosure of "antibodies" and "LL2 antibody," which is a species of B-cell targeting antibody. It more broadly discloses "an antibody or antibody fragment specific to a marker associated with or produced by bone marrow cells," (page 5, lines 19 and 20) and "antibodies and fragments against bone marrow cells, particularly hematopoietic progenitor cells, pancreatic islet cells, spleen cells, parathyroid cells, uterine endometrium, ovary cells, testicular cells, thymus cells, B-cells.. ." (page 12, lines 12-1 6). Accordingly, "an antibody or antibody fragment specific to a marker associated with a B cell" were disclosed in the parent specification and the present claims are not a "departure" from the specification and claims as originally filed.

This is not found persuasive for following reasons:

Contrary to applicant's assertion, neither "an antibody or antibody fragment specific to a marker associated with or produced by bone marrow cells" (see page 5 of the instant specification) nor "the antibodies and fragments against B cells" (see page 12 of the instant specification) is read as "the antibodies and fragments specific to a marker associated with a B cell" as claimed.

Further, the instant specification disclosed one species of the claimed "the antibodies and fragments specific to a marker associated with a B cell", the LL2 antibody. Therefore, applicant's reliance on generic disclosure of antibodies and a single species do not provide sufficient direction and guidance to the features currently claimed "the antibodies and fragments specific to a marker associated with a B cell".

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is once again required to cancel the new matter in the response to this Office Action.

See previous Office Action, mailed 08/17/2006, for detailed analysis.

11. Claims 78-86 and newly added claim 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reason of record.

The following *written description* rejection is set forth herein.

Claim 78-93 recite "an antibody or antibody fragment specific to a marker associated with a B cell" as part of the invention.

Applicant's arguments in conjunction with the references Stein et al (Cancer Immunol Immunother, 1993, 37(5):293-8. abstract only) and Coleman, et al. (Clinical Cancer Research, 2003 9:3991 S-39945) have been fully considered but have not been found persuasive.

Applicant argues that a skilled artisan can readily determine whether an antibody or antibody fragment is specific for a marker associated with a B cell. There exist cultured cell lines that express various B cell antigens, e.g. CD22, and a skilled artisan can readily assess whether an antibody binds to the B cell antigen on these cell lines, and therefore there is a testable functional activity associated with the term "specific for a marker associated with a B cell"; antibodies to other B cell markers can similarly be "tested" with cultured cell lines that express other of the B cell markers, such as CD19 and CD20, and thus antibodies to any of the B cell markers have a testable functional activity and hence are fully described.

Further, applicant asserts that a skilled artisan knows of many B cell antigens (or markers), and could make antibodies to any of these antigens. There is no need for the application to go into detail describing how to make antibodies to various B cell antigens, this is within the level of skill in this art. Nor is there any need for the skilled artisan to know the exact structure of the antibodies so-produced; applicant's contribution is the teaching that antibodies to B cell markers are useful in the treatment of immune diseases.

This is not found persuasive for following reasons:

The issue here is not whether a skilled artisan can make or use the claimed antibody, rather, the instant claims contain subject matter of "an antibody or antibody fragment specific to a marker associated with a B cell" which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Therefore, there is insufficient written description in the specification as-filed of "an antibody or antibody fragment specific to a marker associated with a B cell" as recited in the instant claims.

Applicant further argues that the anti-CD22 antibody, LL2 antibody, is a B cell antibody that has the ability to bind specifically to B cells. The feature that "an antibody or antibody fragment specific to a marker associated with a B cell" possess in common is the ability to bind specifically with a marker associated with a B cell; as such the features allows one skilled in the art to visualize or recognize the identity of the subject matter of the claims.

This is not found persuasive for reasons as stated above. Further, markers associated with a B cells are a diversified large genus that have different structures and physical and/or chemical properties, as such, a single species of LL2 antibody as disclosed in the instant specification is not sufficient to show that applicant is in possession of the claimed genus.

There is no representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties regarding the claimed "an antibody or antibody fragment specific to a marker associated with a B cell" in the instant specification.

Therefore, it does not appear based upon the limited disclosure of a monoclonal LL2 antibody alone that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "an antibody or antibody fragment specific to a marker associated with a B cell".

Applicant is once again directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 78-92 and newly added claim 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg (WO 93/19668) as evidenced by Goldenberg (US Patent 6,183,744) for reasons of record.

Applicant's arguments in conjunction with Goldenberg et al. (J. Clin. Oncol. 1991 Apr. 9, 4:548-564) have been fully considered but have not been found persuasive.

Applicant argues that Goldenberg (WO 93/19668) is the parent of the present application and teaches the presently claimed method of treating an immune disease using antibody or antibody fragment specific to a marker associated with a B cell.

This is not found persuasive because the instant application does not claim priority to Goldenberg (WO 93/19668).

Further, given that the instant claims have been accorded the priority of the filing date of the instant application, i.e. 12/05/2001 (see discussion above in Section 5), the reference of Goldenberg (WO 93/19668) qualifies as 102(b) type reference.

Furthermore, it is noted that a species will anticipate a claim to a genus; a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus. See MPEP 2131.02. In this case, Goldenberg (WO 93/19668) teaches a method of treating immune diseases such as ITP in a subject by using monoclonal LL2 antibody that is specific for a B cell marker CD22; therefore, the reference teaching of method of treating ITP using the LL2 antibody meet the claimed limitation.

Therefore, the reference teachings anticipate the claimed invention.

14. Claims 78-92 and newly added claim 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (US Patent 5, 443,953) for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that Hansen et al. was filed on 12/08/93, after the filing date of the instant application, therefore, the rejection based on Hansen et al. should be withdrawn.

This is not found persuasive for reason because the instant claims have been accorded the priority of the filing date of the instant application, i.e. 12/05/2001 (see discussion above in Section 5), as such the reference of Hansen et al. qualifies as 102(b) type reference.

Therefore the reference teachings anticipate the claimed invention. See previous Office Action, mailed 08/17/2006, for detailed analysis.

15. Claims 78-92 and newly added claim 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Goldenberg et al. (US Patent 7,074,403) for reasons of record.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that Goldenberg et al. has the priority date of 06/09/1999 that is after the priority date of the instant application which is based on US priority date of 04/07/1992.

This is not found persuasive because the instant claims have been accorded the priority of the filing date of the instant application, i.e. 12/05/2001 (see discussion above in Section 5), as such the reference of Goldenberg et al. qualifies as 102(e) type reference.

Therefore the reference teachings anticipate the claimed invention. See previous Office Action, mailed 08/17/2006, for detailed analysis.

16. Claims78-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-140 of US Patent 6,653,104, and claims 1-20 of US Patent 7,074,403 for reasons of record.

Given the absence of additional rebuttal in applicant's amendment to the outstanding nonstatutory obviousness-type double patenting rejections of record over US Patent 6,653,104, and claims 1-20 of US Patent 7,074,403, the rejections are maintained for reasons of record.

17. Claims 78-92 are directed to an invention not patentably distinct from claims 1-17 of commonly assigned claims 1-20 of commonly assigned US Patent 7,074,403 for reasons stated above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US Patent 7,074,403, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

18. Upon further consideration, as well as applicant's amendments, the previous rejection under 35 U.S.C. 112, second paragraph regarding "the therapeutic agent" and rejection under 35 U.S.C. 112, first paragraph, written description against claims 87-92 have been withdrawn.

19. Conclusion: no claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
March 1, 2007

PHILLIP GAMBEL, PH.D JD
PRIMARY EXAMINER
R1600
3/2/07